May 28, 2002

VETERINARY SERVICES MEMORANDUM NO. 800.103

Subject: Reissuance of Product Licenses for Autogenous Products and Guidance Concerning Restrictions on the Production and Use of Veterinary Biologics

To: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics

I. PURPOSE

This Memorandum gives guidance to licensees, permittees, and applicants concerning APHIS restrictions on the production, importation, distribution, and use of autogenous biologics. Effective immediately, the Center for Veterinary Biologics will place restrictions on autogenous products prohibiting the production, distribution, or shipment of autogenous biologics for certain specified animal diseases in accordance with the authority granted to APHIS under 9 CFR 102.5(d).

II. CANCELLATION

This memorandum cancels Veterinary Biologics Memorandum No. 800.103, dated March 5, 2002.

III. BACKGROUND

Currently, APHIS restricts the importation and distribution of veterinary biologics from countries known to have exotic diseases, including but not limited to foot-and-mouth disease, rinderpest, highly pathogenic avian influenza, swine vesicular disease, Newcastle disease, African swine fever, and bovine spongiform encephalopathy, if in the opinion of APHIS, such products may endanger the livestock or poultry of the United States.

In addition, APHIS restricts the production and distribution of veterinary biologics, including but not limited to Brucella Abortus Vaccine, Vesicular Stomatitis Vaccine, and certain diagnostic products used in Cooperative State/Federal/Industry Animal Disease Control and Eradication Programs if it is determined that such products may interfere with disease surveillance and/or control/eradication efforts.

IV. POLICY

The Administrator, APHIS, may restrict distribution of a veterinary biological product if it is determined that the protection of domestic animals or the public health, interest, or safety or both necessitates restrictions on the use of the product and provided that such restrictions are prescribed on the license.

In order to ensure that the production, distribution, and use of autogenous veterinary biologics do not interfere with animal disease surveillance and/or control and eradication programs and do not pose other health risks, the following restriction will be added to licenses for autogenous products:

V. RESTRICTION

This license does not authorize production, distribution, or shipment of autogenous vaccine/bacterin for foot-and-mouth disease, rinderpest, any H5 or H7 subtype of avian influenza, any subtype of avian influenza in chickens, swine vesicular disease, Newcastle disease, African swine fever, classical swine fever, brucella abortus, vesicular stomatitis, and rabbit hemorrhagic disease or any other disease that the Administrator determines may pose a risk to animal or public health.

VI. ADDITIONAL INFORMATION

Contact the Center for Veterinary Biologics-Inspection and Compliance if you have questions concerning whether a particular isolate (microorganism) may be used to produce an autogenous product.

/s/ W. Ron DeHaven

W. Ron DeHaven
Deputy Administrator
Veterinary Services